REMARKS

Amendments

Claim 21 is amended to correct an obvious typographical error. New claims 35-42 are directed to the treatment of certain diseases. See, e.g., page 34, line 8-page 35, line 1; page 35, line 9-12; and page 37, lines 6-17.

Election

Applicants hereby confirm election of Group I, claims 11-26, 33 and 34. While applicants traverse the Restriction, the issue is now moot as the Examiner has rejoined the method claims of Group II, i.e., claims 27-32.

Allowable Subject Matter

Applicants gratefully acknowledge that the claims 11-26, 33 and 34 are allowed.

Rejection under 35 USC §112, first paragraph

Claims 27-32 are rejected under 35 USC §112, first paragraph, on grounds of lack of enablement. This rejection is respectfully traversed.

The rejection initially states that the method claims are enabled "for certain diseases." However, while the rejection fails to specifically state which treatments are enabled, it appears that the only diseases that the Examiner objects to are the treatment of AIDS and Alzheimer's. See, e.g., the top of page 6 of the Office Action where it is asserted that it is "impossible to predict the treatment of certain diseases such as AIDS or Alzheimer's disease." Thus, the Examiner does not object to the treatment of the diseases recited in claims 35-42.

At the bottom of page 5 of the Office Action, the Examiner acknowledges that Miyamoto et al. (US 6,124,276) discloses using vitamin D compounds for the treatment of osteoporosis and as anti-tumor agents. Compare, e.g., applicants' claims 36 and 41.

Also at the bottom of page 5 of the Office Action, it is acknowledged that Reddy (US 6,479,538) discloses using vitamin D compounds in the inhibition of proliferation of skin cells and inducing differentiation in the hyperproliferation of skin cells. Compare, e.g., applicants' claims 35 and 37.

Moreover, Reddy (US '538) discloses using vitamin D compounds: in the treatment of: disorders characterized by aberrant growth or activity of a cell; in the treatment of hyperproliferative skin disorders, e.g., psoriasis; in the inhibition of growth of neoplastic

cells; to modulate an immune response, e.g., in the treatment of lymphoid cells, to suppress immune reactions, to decrease production of lymphokines, and to decrease T cell proliferation; and for treating graft rejection, autoimmunity and inflammation. See column 3, line 64-column 4, line 29. Compare, e.g., applicants' claims 35, 36, and 39.

In addition, US '538 discloses that vitamin D compounds can be used to protect against neuronal loss. As examples of "age-related" neuron loss that can be treated with vitamin D compounds, US '538 lists, among other things, Alzheimer's Disease, Pick's Disease, Parkinson's Disease, and Huntington's Disease.

Thus, contrary to the implication of the Examiner's comments, the art does recognize the use of vitamin D compounds in the treatment of immune disorders (AIDS is an immune disorder) and disorders associated with age related neuron loss such as Alzheimer's.

To further illustrate the spectrum of activities of vitamin D compounds recognized by the art, enclosed herewith is a survey article by Bikle on the activities and uses, both actual and potential, of vitamin D compounds.

In any event, the Examiner's assertion that diseases such as AIDS and Alzheimer's are not treatable by vitamin D compounds is merely conclusory, without any supporting evidence, arguments or rationale. It is by now well settled law that to sufficiently support a rejection for non-enablement, the Examiner can not merely make conclusory arguments, but instead must present reasons or evidence to doubt the veracity of the statements of enablement in the disclosure.

In other words, an application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph 35 U.S.C. § 112, unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. See, e.g., *Marzocchi, In re Brana, 51 F.3d 1560,* 34 USPQ2d 1436 (Fed. Cir. 1995), and *Fiers v. Revel, 984 F.2d 1164,* 24 USPQ2d 1601 (Fed. Cir. 1993). So, to establish non-enablement, an Examiner can not merely say that the treatment of disease X is non-enabled. The Examiner must present reasons why one would doubt that disease X can be treated.

All that is required under the 35 USC 112, first paragraph, is objective enablement. An applicants' disclosure is not required to presents in vivo or in vitro test results. See, e.g., *In re Marzocchi et al.*, 169 USPQ 367, 369(CCPA 1971):

The first paragraph of §112 requires nothing more than objective

enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

The MPEP also agrees by stating that "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." See MPEP § 2164.02.

The test for enablement is not whether any experimentation is needed but whether or not that experimentation is undue. See, *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976) in which the art involved (catalysis) was acknowledged to be unpredictable. Even a considerable amount of experimentation, or complex experimentation, is permissible if it is routine. See, e.g., *Ex parte Jackson,* 217 USPQ 804, 807 (POBA 1982) and *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988).

Merely because it is alleged that a specific example of treating a disease is not presented in the specification, one of ordinary skill in the art would not doubt the truth of the statements concerning the treatment of such diseases. As noted above, MPEP § 2164.02 states that compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. The nature of the invention and the state of the prior art, as discussed above, further demonstrate that applicants' specification provides sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention.

At page 6 of the Office Action, it is asserted that "it is impossible to predict" the treatment of AIDS and Alzheimer's, based on applicants' specification. This is not the test for enablement. Absolute predictability is not required under the statute. Instead, the issue is whether objectively one of ordinary skill in the art can practice the invention using no more the routine experimentation. The rejection presents no rationale to doubt the veracity of statements within applicants' disclosure and no rationale as to why performing experimentation to practice the invention would be undue.

The Examiner argues that the pharmaceutical art exhibits a general lack of predictability. The allegation that the pharmaceutical art is generally unpredictable does not lead to a *per se* conclusion of undue experimentation.

In view of the above remarks, it is respectfully submitted that applicants' disclosure provides more than sufficient guidance to objectively enable one of ordinary skill in the art to

make and use the claimed invention with no more than routine experimentation. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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